UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF ILLINOIS BENTON DIVISION

Tina Lee, individually and on behalf of all others similarly situated,

3:22-cv-01086

Plaintiff,

- against -

Class Action Complaint

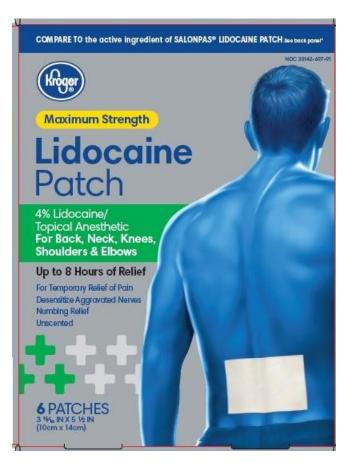
The Kroger Co.,

Jury Trial Demanded

Defendant

Plaintiff alleges upon information and belief, except for allegations pertaining to Plaintiff, which are based on personal knowledge:

1. The Kroger Co. ("Defendant") manufactures, markets, labels and sells "Maximum Strength" adhesive patches promising to deliver 4% lidocaine under the Kroger brand ("Product").



- 2. The Product's front label identifies it as "Lidocaine Patch[es]," that are "Maximum Strength," containing "4% Lidocaine/Topical Anesthetic" that provides relief "For Back, Neck, Knees, Shoulders & Elbows."
- 3. The label promises "Up to 8 Hours of Relief" and that it can be used "[F]or Temporary Relief of Pain," to "[D]esensitize Aggravated Nerves," and provide "[N]umbing Relief."
- 4. Lidocaine is a topical anesthetic used to treat pain by blocking the transmission of pain signals from nerve endings in the skin to the spinal cord and brain.
- 5. Although lidocaine patches can be prescribed by doctors, they are available to consumers as an over-the-counter ("OTC") product.

I. ADHESION FAILURES

- 6. In 2003, the Food and Drug Administration ("FDA") initiated rulemaking to classify products which delivered lidocaine through the skin in a patch form.
- 7. This was because there was no data on "[t]he safe and effective concentration" of lidocaine in this format, and uncertainties regarding the frequency of application that is considered safe and effective.
- 8. However, the FDA concluded that transdermal drug delivery systems, such as the patches used in the Product, systematically fail to adhere to the body.
- 9. The FDA Adverse Events Reporting System reports that approximately 70% of concerns stemming from lidocaine patches involve their poor adhesion.
- 10. A peer-reviewed study published in January of 2021 by the Journal of Pain Research found that 0% of generic prescription lidocaine patches had a >90% adhesion rate to the study's subjects after 12 hours, i.e., essentially no part of the product lifting off the skin.

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- 11. The study also found that after 12 hours, "37.5% of subjects experienced substantial detachment (to <10% adhesion) while using the generic lidocaine patch 5%, including 7 (29.1%) complete detachments."
- 12. The mean adhesiveness score of the generic lidocaine patches after 12 hours was 37.67%, where 0% reflects complete detachment and 50% reflects half the product lifting off the skin but not detached.
- 13. In contrast, a newly developed 1.8% lidocaine patch technology, which is bioequivalent to 5% lidocaine patches, maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).
- 14. Although the study published by the Journal of Pain Research only tested generic prescription lidocaine patches, upon information and belief, Defendant's Product, which has not undergone rigorous approval process required by the FDA and use the same outdated and defective adhesion technology as the generic lidocaine patches, fare no better.
- 15. While certain companies innovated their technology based on clinical studies to ensure that their lidocaine patches reliably adhere to a consumer's body, even while exercising, upon information and belief, Defendant has not.
- 16. The claims that the Product provides "Up to 8 Hours of Relief" is misleading because it regularly peels off the bodies of users within a few hours, and often minutes, after being applied.
- 17. Consumers expect up to eight hours will mean the Product will remains applied for no less than eight hours or even longer.
- 18. The Directions confirm the Product will adhere to the user's skin for the full eight hours because it states to "remove patch from the skin after at most 8 hours of application."

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Directions
Adults and children 12 years of age and over:

If clean and dry affected area
If remove film from patch and apply to the skin (see illustration)
If apply 1 patch at a time to affected area, not more than 3 to 4 times daily
If remove patch from the skin after at most 8 hours of application
Children under 12 years of age: consult a doctor

- 19. However, the Product cannot adhere to the skin for eight hours, which renders the instructions to remove it after eight hours misleading, because it assumes it will not have fallen off by then.
- 20. The result of the failure to adhere to the user's bodies is that the Product does not deliver the "Maximum Strength" amount of lidocaine in patch form.
- 21. Defendant knew the Product did not live up to the adhesiveness representations based on public user comments to websites it actively monitors, and complaints it received from purchasers.
- 22. The Product is prone to greater detachment when engaging in regular activities such as walking, stretching, and sleeping.
- 23. The representation that the Product continuously relieves pain up to eight hours by providing a 4% lidocaine is false and misleading given that it systematically fails to fully adhere to the bodies of users.
- 24. This is crucial because "[a]dequate adhesion is a critical quality attribute for topical delivery systems; if the product lifts or detaches during wear, dosing may be compromised and there is an increased risk of inadvertent exposure to others."

II. MAXIMUM STRENGTH CLAIMS

25. The representation that the Product is "Maximum Strength" is misleading because the actual strength of a lidocaine patch is measured by the "mass of drug relative to the mass of the adhesive per patch," delivered to the target area.

- 26. According to the FDA, when a patch delivering lidocaine becomes "partially detached," its efficacy of delivery and absorption of the active ingredient is greatly reduced.
- 27. The representation that it is "Maximum Strength" tells consumers it contains and delivers the maximum amount of lidocaine available in patch form and is superior, or at least equivalent, in efficacy and results to other OTC and prescription-strength lidocaine patches.
- 28. Numerous studies and reports revealed that users of the adhesive lidocaine patches seldom experience anything close to the promised hours of relief, because the patch fails to adhere for time period promised.

III. DESENSITIZING CLAIMS

- 29. The claim that the Product "Desensitize[s] Aggravated Nerves" and provides "Numbing Relief" "For Back, Neck, Knees, Shoulders & Elbows" is misleading.
- 30. These claims falsely imply the Product completely blocks and desensitizes nerves and pain receptors, eliminates responses to painful stimuli, and can treat neuropathic and musculoskeletal pain, including back and spinal pain.
- 31. Since consumers associate statements about "nerves" with medical treatments requiring a prescription (and FDA approval), this claim tells them the Product can achieve such results.
- 32. Additionally, the FDA determined that statements about "numbing" pain on external analysesic products are misleading to consumers because they are unable to perform this function through a transdermal patch.
- 33. Finally, the claims about nerves and sensitivity are inconsistent with the Product's limited approval "[F]or temporary relief of pain," indicated in the Drug Facts on the back label.



IV. CONCLUSION

- 34. Defendant makes other representations and omissions with respect to the Product which are false and misleading.
- 35. Reasonable consumers must and do rely on a company to honestly and lawfully market and describe the components, attributes, and features of a product, relative to itself and other comparable products or alternatives.
- 36. The value of the Product that Plaintiff purchased was materially less than its value as represented by Defendant.
- 37. Defendant sold more of the Product and at higher prices than it would have in the absence of this misconduct, resulting in additional profits at the expense of consumers.
- 38. Had Plaintiff known the truth, she would not have bought the Product or would have paid less for it.
- 39. As a result of the false and misleading representations, the Product is sold at a premium price, approximately no less than no less than \$8.99 for six patches, excluding tax and sales, higher than similar products, represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

Jurisdiction and Venue

- 40. Jurisdiction is pursuant to Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).
- 41. The aggregate amount in controversy exceeds \$5 million, including any statutory damages, exclusive of interest and costs.
 - 42. The Product has been sold at thousands of locations in the states covered by the

classes Plaintiff seeks to represent, with the representations challenged here, for at least 10 years.

- 43. Plaintiff Tina Lee is a citizen of Illinois.
- 44. Defendant The Kroger Co. is a Ohio corporation with a principal place of business in Cincinnati, Hamilton County, Ohio.
- 45. The members of the class Plaintiff seeks to represent are more than 100, because the Product has been sold with the representations described here for several years, in thousands of locations, in the states covered by Plaintiff's proposed classes.
 - 46. The Product is available to consumers from Defendant's retail stores and its website.
- 47. Venue is in the Benton Division in this District because a substantial part of the events or omissions giving rise to these claims occurred in Cook County, including Plaintiff's purchase, consumption, transactions and/or use of the Product and awareness and/or experiences of and with the issues described here.

Parties

- 48. Plaintiff Tina Lee is a citizen of Fairfield, Cook County, Illinois.
- 49. Defendant The Kroger Co. is a Ohio corporation with a principal place of business in Cincinnati, Ohio, Hamilton County.
- 50. Founded by Bernard Kroger in 1883 in Cincinnati, Ohio, Kroger is the largest supermarket chain in the United States.
- 51. Kroger is responsible for numerous innovations in the way Americans shop, and has expanded beyond groceries to non-consumable products, even providing medical services.
 - 52. Kroger is ranked first among grocery stores when it comes to consumer trust.
 - 53. This trust has been built up over the one hundred plus years in business.
 - 54. Communities and customers remember how Kroger pitched in to help them out in

times of crisis and emergency.

- 55. Even though many smaller stores no longer exist in many towns, Kroger has successfully provided the same level of attention and caring customers once received at their "Main Street" stores.
- 56. While Kroger stores sell leading national brands, they sell a large number of products under one of their private label brands, Kroger.
- 57. Private label products are made by third-party manufacturers and sold under the name of the retailer, or its sub-brands.
- 58. Previously referred to as "generic" or "store brand," private label products have increased in quality, and often are superior to their national brand counterparts.
- 59. Products under the Kroger brand have an industry-wide reputation for quality and value.
- 60. In releasing products under the Kroger brand, Defendant's foremost criteria was to have high-quality products that were equal to or better than the national brands.
- 61. Defendant is able to get national brands to produce its private label items due its loyal customer base and tough negotiating.
- 62. That Kroger branded products met this high bar was proven by focus groups, which rated them above the name brand equivalent.
- 63. Private label products generate higher profits for retailers because national brands spend significantly more on marketing, contributing to their higher prices.
- 64. A survey by The Nielsen Co. "found nearly three out of four American consumers believe store brands are good alternatives to national brands, and more than 60 percent consider them to be just as good."

- 65. Private label products under the Kroger brand benefit by their association with consumers' appreciation for the Kroger brand as a whole.
- 66. The development of private label items is a growth area for Kroger, as they select only top suppliers to develop and produce Kroger products.
- 67. Plaintiff purchased the Product at locations including Kroger, 415 S 42nd St Mount Vernon IL 62864-6266, between May 20, 2020 and May 20, 2021, among other times.
- 68. Plaintiff believed and expected the Product provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised because that is what the representations and omissions said and implied, on the front label and the absence of any reference or statement elsewhere on the Product.
- 69. Plaintiff saw the Product was labeled and marketed as "Maximum Strength" capable of delivering a 4% lidocaine dose for "UP TO 8 HOURS" and read the directions on the back label, which indicated that she could use one patch for eight hours.
- 70. Plaintiff saw those representations prior to and at the time of her purchases and understood them as a representation and warranty that the Product would reliably adhere to her body and deliver a 4% lidocaine dose for 8 hours.
- 71. Plaintiff relied on the words, terms coloring, descriptions, layout, placement, packaging, hang tags, and/or images on the Product, on the labeling, statements, omissions, claims, statements, and instructions, made by Defendant or at its directions, in digital, print and/or social media, which accompanied the Product and separately, through in-store, digital, audio, and print marketing.
 - 72. Plaintiff bought the Product at or exceeding the above-referenced price.
 - 73. Plaintiff would not have purchased the Product if she knew the representations and

omissions were false and misleading or would have paid less for it.

- 74. Plaintiff chose between Defendant's Product and products represented similarly, but which did not misrepresent their attributes, requirements, instructions, features, and/or components.
- 75. The Product was worth less than what Plaintiff paid and she would not have paid as much absent Defendant's false and misleading statements and omissions.
- 76. Plaintiff intends to, seeks to, and will purchase the Product again when she can do so with the assurance the Product's representations are consistent with its abilities, attributes, and/or composition.
- 77. Plaintiff is unable to rely on the labeling and representations not only of this Product, but other similar adhesive lidocaine patches, because she is unsure whether those representations are truthful.

Class Allegations

78. Plaintiff seeks certification under Fed. R. Civ. P. 23 of the following classes:

Illinois Class: All persons in the State of Illinois who purchased the Product during the statutes of limitations for each cause of action alleged; and

Consumer Fraud Multi-State Class: All persons in the States of Virginia, Montana, Wyoming, Idaho, Alaska, Virginia, Kentucky, West Virginia, Kansas, Nebraska, North Dakota, Iowa, Mississippi, Arkansas, South Carolina and Utah who purchased the Product during the statutes of limitations for each cause of action alleged.

- 79. Common questions of issues, law, and fact predominate and include whether Defendant's representations were and are misleading and if Plaintiff and class members are entitled to damages.
 - 80. Plaintiff's claims and basis for relief are typical to other members because all were

subjected to the same unfair, misleading, and deceptive representations, omissions, and actions.

- 81. Plaintiff is an adequate representative because her interests do not conflict with other members.
- 82. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.
- 83. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.
- 84. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.
 - 85. Plaintiff seeks class-wide injunctive relief because the practices continue.

Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/1, et seq.

(Consumer Protection Statute)

- 86. Plaintiff incorporates by reference all preceding paragraphs.
- 87. Plaintiff believed the Product provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised.
- 88. Defendant's false, misleading and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.
- 89. Defendant misrepresented the Product through statements, omissions, ambiguities, half-truths and/or actions.
- 90. Plaintiff relied on the representations and omissions to believe the Product provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised.
 - 91. Plaintiff would not have purchased the Product or paid as much if the true facts had

been known, suffering damages.

Violation of State Consumer Fraud Acts

(On Behalf of the Consumer Fraud Multi-State Class)

- 92. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class are similar to the consumer protection statute invoked by Plaintiff and prohibit the use of unfair or deceptive business practices in the conduct of commerce.
- 93. The members of the Consumer Fraud Multi-State Class reserve their rights to assert their consumer protection claims under the Consumer Fraud Acts of the States they represent and/or the consumer protection statute invoked by Plaintiff.
- 94. Defendant intended that members of the Consumer Fraud Multi-State Class would rely upon its deceptive conduct.
- 95. As a result of Defendant's use of artifice, and unfair or deceptive acts or business practices, the members of the Consumer Fraud Multi-State Class sustained damages.
- 96. Defendant's conduct showed motive and a reckless disregard of the truth such that an award of punitive damages is appropriate.

Breaches of Express Warranty, Implied Warranty of Merchantability/Fitness for a Particular Purpose and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, et seq.

- 97. The Product was manufactured, identified, marketed and sold by Defendant and expressly and impliedly warranted to Plaintiff that it provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised.
- 98. Defendant directly marketed the Product to Plaintiff through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, product descriptions distributed to resellers, and targeted digital advertising.

- 99. Defendant knew the product attributes that potential customers like Plaintiff were seeking and developed its marketing and labeling to directly meet those needs and desires.
- 100. Defendant's representations about the Product were conveyed in writing and promised it would be defect-free, and Plaintiff understood this meant that it provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised.
- 101. Defendant's representations affirmed and promised that the Product provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised.
- 102. Defendant described the Product so Plaintiff believed it provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised, which became part of the basis of the bargain that it would conform to its affirmations and promises.
- 103. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.
- 104. This duty is based on Defendant's outsized role in the market for this type of Product, a trusted company known for its high quality products.
 - 105. Plaintiff recently became aware of Defendant's breach of the Product's warranties.
- 106. Plaintiff provided or will provide notice to Defendant, its agents, representatives, retailers, and their employees.
- 107. Plaintiff hereby provides notice to Defendant that it breached the express and implied warranties associated with the Product.
- 108. Defendant received notice and should have been aware of these issues due to complaints by third-parties, including regulators, competitors, and consumers, to its main offices,

and by consumers through online forums.

- 109. The Product did not conform to its affirmations of fact and promises due to Defendant's actions.
- 110. The Product was not merchantable because it was not fit to pass in the trade as advertised, not fit for the ordinary purpose for which it was intended and did not conform to the promises or affirmations of fact made on the packaging, container or label, because it was marketed as if it provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised.
- 111. The Product was not merchantable because Defendant had reason to know the particular purpose for which the Product was bought by Plaintiff, because she expected it provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised, and she relied on Defendant's skill and judgment to select or furnish such a suitable product.
- 112. Plaintiff would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Negligent Misrepresentation

- 113. Defendant had a duty to truthfully represent the Product, which it breached.
- 114. This duty was non-delegable, based on Defendant's position, holding itself out as having special knowledge and experience in this area, a trusted company known for its high quality products.
- 115. Defendant's representations and omissions regarding the Product went beyond the specific representations on the packaging, as they incorporated the extra-labeling promises and commitments to quality, transparency and putting customers first, that it has been known for.

- 116. These promises were outside of the standard representations that other companies may make in a standard arms-length, retail context.
- 117. The representations took advantage of consumers' cognitive shortcuts made at the point-of-sale and their trust in Defendant.
- 118. Plaintiff reasonably and justifiably relied on these negligent misrepresentations and omissions, which served to induce and did induce, their purchase of the Product.
- 119. Plaintiff would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Fraud

- 120. Defendant misrepresented and/or omitted the attributes and qualities of the Product, that it provided maximum strength lidocaine in the percent indicated, to the areas referenced, and for the time period promised.
- 121. Moreover, the records Defendant is required to maintain, and/or the information inconspicuously disclosed to consumers, provided it with actual and constructive knowledge of the falsity and deception, through statements and omissions.
 - 122. Defendant knew of the issues described here yet did not address them.
- 123. Defendant's fraudulent intent is evinced by its knowledge that the Product was not consistent with its representations.

Unjust Enrichment

124. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of Plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying Plaintiff as representative and the

undersigned as counsel for the class;

2. Entering preliminary and permanent injunctive relief by directing Defendant to correct the

challenged practices to comply with the law;

3. Injunctive relief to remove, correct and/or refrain from the challenged practices and

representations, and restitution and disgorgement for members of the class pursuant to the

applicable laws;

4. Awarding monetary damages, statutory and/or punitive damages pursuant to any statutory

claims and interest pursuant to the common law and other statutory claims;

5. Awarding costs and expenses, including reasonable fees for Plaintiff's attorneys and

experts; and

6. Other and further relief as the Court deems just and proper.

Dated: May 23, 2022

Respectfully submitted,

/s/Spencer Sheehan

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